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Original Article

Prospective randomized study of axillary venous access with or without fluoroscopy-guided in cardiovascular implantable electronic device implantation

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Abstract: Purpose: Axillary venous access is a safe and effective method for cardiovascular implantable electronic device (CIED) implantation with less complications compared with subclavian vein puncture technique. The study aimed to assess the safety and efficacy of axillary vein puncture with or without fluoroscopy-guided. Methods: A total of 600 patients referred for CIED implantation were randomly assigned to axillary vein puncture with fluoroscopy-guided group (n = 300) or Blind axillary vein puncture without fluoroscopy-guided group (n = 300). The total success rate of vein access, the success rate of one single attempt, the vein access duration (from skin incision to a guide wire in the inferior vena cava, as attested by fluoroscopy), the procedure duration (from skin incision to skin closure), X-ray exposure, fluoroscopy duration, and complications in the perioperative and follow-ups were recorded. Results: The rate of success was higher in the group of axillary vein puncture using fluoroscopy-guided than that in the group without fluoroscopy-guided (97.67% vs 72.00%, P < 0.001). The fluoroscopy-guided axillary vein puncture was successful at the first attempt in 192 punctures (64.00%), as vs 114 (38.00%) in the group without fluoroscopy-guided (P < 0.001). The time of venous access was shorter in the fluoroscopic axillary vein puncture group than that in the blind axillary vein puncture group (91.6±10.68 vs 141.5±12.21 sec, P < 0.001), as well as procedure duration (55.7±7.50 vs 62.9±4.32 min, P < 0.001). X-ray exposure and complications in the perioperative and follow-ups were comparable in the two groups. Conclusions: The fluoroscopically guided axillary venous access for CIED implantation may be superior to the blind axillary venous access without fluoroscopy-guided and has shorter procedural time to access the vein and fewer complications.

Keywords: Axillary vein puncture, cardiovascular implantable, electronic device

Introduction

A safe and fast central venous access is the basis for successful implantation of cardiovascular electronic devices (CIED). According to regional standards, specifications of the center or operators' personal preferences, the choice of vascular access varies greatly. In a recent survey by the European heart rhythm association (EHRA), Bongiorni et al. reported that 60 percent of the European centers used cephalic veins, and about 20 percent chose the subclavian or axillary veins as the initial vascular pathway for CIED implantation. Among these venous access methods used for CIED implantation, the subclavian vein puncture technique first introduced by Littleford in 1979 [1] is the most widely used at present in China. It is relatively easy to learn, and obtains high rates of success, but it may be associated with acute complications such as pneumothorax, hemothorax, brachial plexus injury [2, 3], or chronical complications including loss of lead insulation, lead fracture, subclavian crush syndrome, and difficulty in lead operating [4-10].

In contrast, the axillary venous approach is an alternative vascular access for CIED implantation. The axillary vein is a continuation of the subclavian vein, which is large enough to accommodate multiple leads. In the long term compared with subclavian venous approach, it has been demonstrated that axillary vein is a safe and effective method with less lead failures and less complication [11-19].

At present, the techniques of axillary vein puncture mainly include blind axillary vein puncture

without fluoroscopy-guided, fluoroscopy guided puncture, caudal fluoroscopy, contrast-venography guided puncture, ultrasound guided puncture, etc. Although contrast-venography guided puncture is currently the most popular technique which is easy to learn and is safely and effectively for most operators to perform, it is expensive and not always successful, and has limited usefulness in patients with contrast allergy or severe renal insufficiency. In contrast, blind axillary vein puncture without fluoroscopy-guided and fluoroscopy guided puncture are more economical and convenient on the premise of safety. Therefore, our experience of axillary vein puncture with or without fluoroscopy-guided in this paper.

Methods

Patient population and randomization

Consecutive patients referred to our department from January 2015 to January 2017 for permanent pacemakers (PM), implantable cardioverter defibrillators (ICD), and cardiac resynchronization therapy pacemakers/defibrillators (CRT-P/CRT-D) were prospectively evaluated using axillary vein puncture as the primary approach. The study was approved by the Institutional Review Board of Renmin Hospital of Wuhan University, and all patients gave their informed consent. Patients undergoing lead or PM replacement and those unable to provide informed consent were excluded from the study.

According to a randomization list, all patients were randomized to axillary vein puncture with fluoroscopy-guided group (group A, n = 300) or without fluoroscopy-guided group (group B, n = 300) at a ratio of 1:1. The pulse generators were implanted on the surface of the pectoralis major on the same side. Operations in both groups were performed consistently by two experienced electrophysiology physicians.

Fluoroscopy-guided axillary vein puncture

Before the needle puncture, a skin incision was made, which was parallel and approximately 2-3 cm below to the clavicle and approximately 1.5-2 cm medial to the deltopectoral groove and a pocket was created. An 18-gauge needle was attached to a 10 ml-syringe. The needle with continuous suction on the syringe was pointed and advanced toward landmarks consisting of the lateral edge of the first rib below the inferior border of the clavicle or the second rib meeting the thoracic cage in the fluoroscopic posterior-anterior view of the chest. The needle was maintained in the position with an angle of approximately 45°-80° (depending on the body habitus) between the needle and the horizontal plane and subsequently advanced until venous blood was aspirated; or the needle was then advanced until the first rib was struck. The needle and the syringe were then slowly withdrawn under suction until the vein was entered. Care is taken to not cross the first rib, which may result in pneumothorax. Once the venous structure was entered, a guide wire was inserted and positioned in the inferior vena cava. In case the first attempt of the vein was not entered, the needle was withdrawn and advanced again with slight adjustments in the puncture angle. If 3 attempts of puncture failed, contrast-guided vein puncture was performed as previously described.

Blind axillary vein puncture without fluoroscopy-guided

The technique of blind axillary vein puncture without fluoroscopy-guided was a modified version of the technique used by Belott [20]. The patients were placed in a supine position. Before needle puncture, a skin incision was made, and a pocket was created. The needle attached to a 10 ml-syringe at an angle of approximately 45°-60° relative to the body's surface was advanced parallel and approximately 2 cm medial to the deltopectoral groove, as Belott's description in the study. Occasionally, when the needle tip touched the first rib, the needle with continuous suction on the syringe was withdrawn until the vein was entered. A maximum of 3 attempts was allowed per case. If 3 attempts of puncture failed, fluoroscopy-guided or contrast-guided vein puncture was performed.

Common parts of the two study groups in the procedure and follow-up

Before the procedure, all patients underwent intravenous antibiotic prophylaxis. After vein access, procedures were identical in two study groups, and were performed according to the standard manner. Active -fixation bipolar endocardial leads were used in all patients. Right ventricle leads were positioned on the median interventricular septum, and atrial leads target-

Table 1. Patients characteristics

Patients Characteristics	Fluoroscopic axillary vein puncture group (n=300)	Blind axillary vein puncture group (n=300)	*P*-value
Age (y)	62 [45-80] 62.8±6.68	61 [43-83] 61.94±6.00	0.09
Female gender	105 (35.0%)	103 (34.3%)	0.86
Diabetes mellitus	55 (18.3%)	59 (19.6%)	0.67
Hypertension	136 (45.3%)	132 (44.0%)	0.74
Cardiopathy (any)	104 (34.6%)	99 (33.0%)	0.67
Antiplatelet	28 (9.3%)	27 (9.0%)	0.34
Double antiplatelet	3 (1%)	4 (1.3%)	0.70
VK antagonist	1 (0.3%)	0	0.32
Active smoking	167 (55.6%)	171 (57.0%)	0.74

VK, Vitamin K.

ed the right atrial septum or the right atrial appendage. The pacemaker was placed in a left pre-pectoral pocket, and skin was closed by overlock suturing with non-absorbable thread.

After the procedure, a routine chest X-ray was obtained at 24 hours to assess lead position and to rule out the evidence of pneumothorax. The suture and pacemaker pocket were examined daily. The follow-up period was about 1 year. The follow-up data were obtained prospectively during regular outpatient visits at 1 week, 3 month, 6 month and 1 year. Complications included accidental axillary artery puncture, pneumothorax, hemopneumothorax, chest hematoma, subclavian crush, brachial plexus, pocket bleeding, dislodged lead, and venous embolism.

Endpoints

Assessment of the effectiveness of the fluoroscopic axillary vein puncture was compared with that of the blind axillary vein puncture including the overall success of vein access, the success of a single attempt, the vein access duration (from skin incision to a guide wire in the inferior vena cava, as attested by fluoroscopy), and the procedure duration (from skin incision to skin closure).

Safety of the both groups was compared by recording X-ray exposure and fluoroscopy duration, as well as complications of the periprocedural and follow-up.

Statistical analysis

Categorical variables are expressed as frequencies (%). Continuous variables are expressed as mean ± SD. Categorical differences between groups were compared with the χ^2 test or the Fisher exact test as appropriate. Continuous variables were compared with Student's *t* test for paired sample (two-sided); $P < 0.05$ was considered statistically significant.

Results

A total of 600 patients were enrolled into the study. Baseline characteristics of the two groups are summarized in **Table 1**. There were no significant differences in gender, age, medical condition, or types of CIED between the two groups.

Axillary vein puncture with fluoroscopy-guided group was successful in 293 out of the 300 patients (97.67%), as compared with blind axillary vein puncture group, which was successful in 216 out of 300 patients (72.00%; $P < 0.001$ for fluoroscopic axillary vein puncture group vs blind axillary vein puncture group). In the fluoroscopic axillary vein puncture group 192 cases, axillary vein access could be obtained in a single attempt (64%), as vs 114 cases in blind axillary vein puncture (38%; $P < 0.001$). The average time taken to obtain a venous access was 91.6 seconds in fluoroscopic axillary vein puncture group, compared with 141.5 seconds in blind axillary vein puncture group ($P < 0.001$; **Table 2**).

When the vein punctures failed in patients, contrast-guided vein puncture was performed and the puncture was performed under the guidance of angiography. There was also no hemothorax. Six patients (2.0%) in blind axillary vein puncture group had pneumothorax. Five of the 6 did not require any intervention, while one patient required insertion of a chest tube for the pneumothorax. Only one patient had pneumothorax in fluoroscopic axillary vein puncture group. Accidental axillary artery puncture was occurred in three patients in blind axillary vein puncture group, none in fluoroscopic axillary vein puncture.

Table 2. Procedural data and periprocedural or follow-up complications

Procedural and complications data	Fluoroscopic axillary vein puncture group (n=300)	Blind axillary vein puncture group (n=300)	*P*-value
Procedural data			
Overall success of vein access	293 (97.67%)	216 (72.00%)	< 0.001
Success of a single attempt	192 (64.00%)	114 (38.00%)	< 0.001
Vein access duration (sec)	91.6±10.68	141.5±12.21	< 0.001
procedure duration (min)	55.7±7.50	62.9±4.32	< 0.001
X-Ray exposure (mGycm^2)	1237.61±79.59	1219.32±165.73	0.09
Fluoroscopy duration (min)	3.6±0.56	3.4±0.75	0.06
Double-chamber PM implanted	267 (89.00%)	271 (90.33%)	0.59
Double-chamber PM implanted	267 (89.00%)	271 (90.33%)	0.59
Single-chamber PM implanted	12 (4.00%)	10 (3.33%)	0.66
Double-chamber ICD implanted	11 (3.67%)	12 (4.00%)	0.83
Single-chamber ICD implanted	6 (2.00%)	4 (1.33%)	0.52
CRT implanted	4 (1.33%)	3 (1.00%)	0.70
Complications data			
Pneumothorax	1 (0.33%)	6 (2.00%)	0.06
Haemothorax	0	0	NA
Pocket haematoma	3 (1.00%)	4 (1.33%)	0.70
Pericardial effusion	1 (0.33%)	0	0.32
Brachial plexus transient palsy	0	1 (0.33%)	0.32
Axillary artery puncture	0	3 (1.00%)	0.08
Lead dislodgement	0	0	NA
Lead fracture	0	0	NA
Subclavian crush syndrome	0	0	NA
Total complications	5 (1.67%)	12 (4.00%)	0.09

During a mean follow-up of 13.1±2.4 months, there was no evidence of subclavian crush, lead fracture, or dislodgement in two groups. One patient in group B had a clinically significant hematoma in pocket at 1 week follow up. One patient in blind axillary vein puncture group was found to have a brachial plexus, with complaints of left-arm difficulty lifting, which was adjudicated to be related to the axillary puncture. The patient's symptoms vanished at the 3-month follow-up. There was a non-significant variation in lead impedance, pacing, or sensing parameters between the both study groups during follow-up.

Discussion

The study was designed to evaluate the safety and effectiveness of axillary vein puncture with fluoroscopy-guided for CIED implantation. The study findings were that (1) the axillary vein puncture with fluoroscopy-guided was both effective and practicable, (2) it had been demonstrated to be safe, and (3) the rate of successful puncture was higher using the outer edge of the first rib as fluoroscopic landmark compared with blind axillary vein puncture using anatomic landmark (293/300, 97.67% vs 216/300, 72.00%; P < 0.001).

The axillary venous approach for device implantation was first introduced by Byrd [21]. Subsequently, some physicians expanded and improved various different techniques of axillary vein puncture ranging from the use of different tools such as ultrasound and contrast venography [11-19] to a blind percutaneous puncture.

Blind axillary vein puncture using the delto-pectoral groove as a anatomic landmark on body surface was used successfully by Belott in 165 of 168 patients [20]. Jiang M et al. [22] reported a 94% success rate of axillary vein puncture with shallow needle trajectory. However, the high success rate has only been reported by a single medical center, and other physicians have been reluctant to use an unguided stick. In this study, the success rate in the group without fluoroscopy-guided was only 72%. Furthermore, the overall success rate and a single attempt success rate of fluoroscopic axillary venous access was very high and comparable. The technique of fluoroscopic axillary vein puncture is noteworthy because it avoids the need of contrast venography, and needs less procedural time with low complication rate, compared with the blind axillary vein puncture.

Six patients (2.00%) in the blind axillary vein puncture group had pneumothorax. Pneumothorax after axillary vein puncture using fluo-

roscopy-guided or contrast venography demonstrated a lower incidence in the literature (0%) [22-24] than that in our study (2.00%), emphasizing the fact that this particular minor complication may more frequently happen during the blind axillary vein puncture without fluoroscopy-guided treatment. Because the angle of approximately 45°-60° relative to the body's surface can easily lead the needle to enter the thorax and injure the lungs. In the fluoroscopic axillary vein puncture group, however, during axillary vein puncture, the anterior part of the first rib forms a natural barrier and is very reassuring by preventing the needle from passing through the intercostal space and causing a pneumothorax. After axillary vein puncture using fluoroscopic landmarks without contrast venography, brachial plexuspalsy in the literature showed a low incidence from 0% to 1.3%, [22, 23] as well as that in our centre. However, brachial plexuspalsy might happen during axillary vein puncture and therefore one should avoid lateral punctures and deep lidocaine injections, which should pay a special attention [24].

Limitations

Our study has several limitations. First, it is a monocentric study, with a relatively small cohort size. Second, the follow-up was relatively short, and we could not observe any device-related complications, or evaluate long-term efficacy. Third, fluoroscopy duration and X-ray exposure were both comparable in the fluoroscopic axillary vein puncture group and blind axillary vein puncture group, nevertheless the small number of patients included may explain this finding since axillary vein was sought using fluoroscopic landmarks, whereas blind axillary vein puncture group was anatomic landmarks. Therefore it is conceivable that with a larger study group of patients, fluoroscopy duration and X-ray exposure have been significantly higher in the fluoroscopic axillary vein puncture group.

Conclusion

In light of the higher success rate and the shorter procedure time, with fewer complications, it is proposed that a fluoroscopy-guided axillary venous access to implanting CIED may be superior to the blind axillary vein puncture access.

Disclosure of conflict of interest

None.

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